ANNEX B

List of Product Information File (PIF) Audit Deficiencies

The classification of deficiencies are as follows. The list is non-exhaustive and other observations may be added, removed, or re-classified as appropriate.

Non-inclusion of a non-conformance against the ASEAN Cosmetic Directive, any standard, rule and regulation, shall not preclude the PIF Auditor to assign a classification in this list. In the assignment of classifications for such observations/findings, the PIF Auditor shall be guided by the definitions provided for Critical, Major, and Other Deficiencies in this Circular. The FDA shall endeavour to publish an updated list, based on the review of the implementation of this Circular.

1. Critical

- Lack of or incomplete PIF Document (i.e., technical documents which may affect the product quality and safety).
- The MAH and/or the manufacturer has no valid License to Operate.
- Deviation from the approved LTO authorization for manufacturer (e.g., product line).
- The product contains a banned ingredient based on ACD.
- The restricted ingredient declared on the CPN and/or qualitative and quantitative formula of the product has exceeded the maximum allowable concentration based on ACD Annexes.
- The use of the ingredient is not allowed for its product type.
- Lack of or incomplete Technical Specifications for each ingredient.
- Lack of or incomplete COA for each ingredient.
- Unsigned/Unverifiable Certificate of Analysis (COA) for each ingredient.
- The ingredients indicated on the actual commercial sample are inconsistent with the CPN and/or the qualitative and quantitative formula of the product.
- Lack of Technical Specifications for finished product.
- Lack of Test Method for finished product.
- Lack of COA for finished product.
- Unsigned/Unverifiable Certificate of Analysis (COA) of finished product.
- Out-of-specification test results not properly investigated and documented according to SOP.
- Evidence of falsification or misrepresentation of analytical results.
- The manufacturer from non-ASEAN Member States (non-AMS) has no GMP Certificate or its equivalent.
- No Batch Manufacturing/Packaging Records.
- Evidence of falsification or misrepresentation of Batch Manufacturing Record.
- There is no Summary of Safety Assessment for the product.
- No data available to establish the shelf-life of the product.

2. Major

- Incomplete PIF Document (i.e., administrative documents)
- Deviation from the approved LTO authorization for Market Authorization Holder (e.g., LTO activity).

- Lack of or incomplete tests/substantiation/justification for ingredients with specific requirements as laid down in the ACD Annexes and/or FDA issuances (e.g., Petrolatum, Triethanolamine, Talc).
- The required labelling information as per ACD Appendix II is not declared on the label.[1]
- The conditions of use and warnings and other limitations and requirements laid down in the ACD Annexes are not printed on the label.[1]
- Lack of SOP for Batch Coding/Numbering.
- Deviations from batch manufacturing instructions during production.
- Unsigned Summary of Safety Assessment.
- Insufficient data to establish the shelf-life of the product
- Lack of SOP for Handling of Consumer Complaints and Adverse Event Reports.
- The intended and/or direction for use/ target area/ product claim is not appropriate for a cosmetic product.[1]
- Lack of or incomplete tests/substantiation/justification for on-pack claims.

3. Others

- The PIF is not written in English or Filipino Language.
- Lack of or incomplete safety data for each ingredient.
- The ingredients are not specified using the nomenclature from the latest edition of standard references, the botanical ingredients and extracts of botanicals are not identified by its genus and species.
- There is no actual commercial sample presented.
- The address of the MAH reflected on the label is inconsistent with the LTO and/or CPN.
- The country of manufacture reflected on the label is inconsistent with the information declared in the CPN.
- The qualifications/curriculum vitae of the safety assessor is not provided.
- Lack of certificate of compliance to latest IFRA guidelines (for fragrance materials)

[1] For these findings, the PIF Auditor may impose additional regulatory actions (i.e. Issuance of Notice of Product Recall) if circumstances require.